

### ***Remarks***

Applicants have amended the title of the application and updated the status of applications in the benefit claim in paragraph [0001] as requested by the Examiner. Applicants have also canceled claims 32-33 and amended claims 21, 23-24, 29 and 34 without prejudice or disclaimer. The amendments find support throughout the specification as originally filed and as noted more specifically below, and thus no new matter has been added.

Claims 21 to 31 and 34 to 35 are pending.

#### **I. Objections to the Specification**

The Examiner has objected to the specification, noting that the status of applications in the benefit claim in paragraph [0001] has not been updated and that the title of the application has not been amended to reflect the presently claimed invention. In response, Applicants have amended the application as requested by the Examiner, thereby obviating the objections.

#### **II. Objections to the Claims**

The Examiner has objected to the claims, noting that claims 28 and 32 appear to be duplicates. In response, Applicants have canceled claim 32, thereby obviating the objection.

#### **III. Rejections of Claim 33 Under 35 U.S.C. §§ 101 and 112, First Paragraph**

The Examiner has rejected claim 33 under 35 U.S.C. §§ 101 and 112, first paragraph, as allegedly not complying with the utility requirement. In response, while Applicants do not acquiesce with the instant rejections, claim 33 has been canceled without prejudice or disclaimer, thereby obviating the rejections. Accordingly, Applicants respectfully request that the rejections be reconsidered and withdrawn.

#### **IV. Rejections Under 35 U.S.C. § 112, First Paragraph**

##### **A. Claims 21-35**

The Examiner has rejected claims 21-35 under 35 U.S.C. § 112, first paragraph, as allegedly adding matter with respect to the “at least 30 contiguous amino acid residues of SEQ ID NO:2” language present in claim 21. In response, while Applicants do not acquiesce with the instant rejection, claim 21 has been amended without prejudice or disclaimer to recite instead “amino acid

residues 1 to 303 of SEQ ID NO:2,” thereby obviating the rejection. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

**B. Claim 23**

The Examiner has rejected claim 23 under 35 U.S.C. § 112, first paragraph, as allegedly adding matter with respect to methods in which antibodies are bound to a solid support other than competitive-binding assays. In response, while Applicants do not acquiesce with the instant rejection and maintain that other assays using bound antibodies are well-known in the art, claim 23 has been amended without prejudice or disclaimer to recite that the assay is a competitive-binding assay, thereby obviating the rejection. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

**C. Claim 24**

The Examiner has rejected claim 24 under 35 U.S.C. § 112, first paragraph, as allegedly adding matter with respect to limitations regarding the reporter antibody.

In response, Applicants respectfully disagree and traverse. Applicants note that claim 24 has been amended without prejudice or disclaimer to specify that the reporter antibody binds the antibody or fragment thereof recited in claim 21 (which binds a polypeptide consisting of amino acid residues 1 to 303 of SEQ ID NO:2). However, Applicants disagree with the Examiner’s contentions that (1) the reporter antibodies are only prepared against monoclonal antibodies of the invention; and (2) the reporter antibodies must be specific to monoclonal anti-ICE-LAP 3 antibodies. First, paragraph [0095] of the application recites that the anti-ICE-LAP 3 antibodies for use in the exemplary ELISA assays are “preferably a monoclonal antibody.” The use of polyclonal reporter antibodies is clearly encompassed in paragraph [0095] and was well-known in the art (*see, e.g.,* U.S. Patent No. 5,773,280 at column 5, lines 45-47), and it is not proper to require the claims to be limited only to a preferred embodiment. *See, e.g.,* M.P.E.P. § 2111.01(II). Second, it was well-known in the art that reporter antibodies needed to bind to the antibody being detected, but need not be specific to such antibodies to the exclusion of other antibodies. For example, antibodies from a second species (*i.e.,* goat anti-mouse antibodies) were commonly used as reporter antibodies to detect antibodies of a first species. *See, e.g.,* U.S. Patent No. 5,773,280 at column 5, lines 45-47.

Accordingly, claim 24 as amended is fully supported by the specification and does not add new matter. Thus, Applicants respectfully request that the rejection be reconsidered and withdrawn.

**D. Claim 29**

The Examiner has rejected claim 29 under 35 U.S.C. § 112, first paragraph, as allegedly adding matter with respect to human antibodies.

In response, Applicants respectfully disagree and traverse. Applicants note that claim 29 has been amended without prejudice or disclaimer to depend from claim 26 (monoclonal antibodies) rather than claim 21. Applicants also direct the Examiner's attention to paragraph [0106] of the application, which recites "human monoclonal antibodies" that can be produced using the well-known human B-cell hybridoma and EBV-hybridoma techniques.

Accordingly, claim 29 as amended is fully supported by the specification and does not add new matter. Thus, Applicants respectfully request that the rejection be reconsidered and withdrawn.

**V. Rejections Under 35 U.S.C. § 112, Second Paragraph**

The Examiner has rejected claim 34 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite due to the recitation of "said tissue sample." In response, claim 34 has been amended without prejudice or disclaimer to recite "said sample," which finds antecedent basis in claim 21(a), thereby obviating the rejection. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

**VI. Rejections for Alleged Obviousness-Type Double Patenting**

The Examiner has rejected claims 21-35 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-61 of U.S. Patent No. 6,733,981 and various secondary references.

Although Applicants do not acquiesce with the instant rejection, Applicants have submitted herewith a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c), thereby obviating the instant rejection. Accordingly, Applicants respectfully request that the obviousness-type double patenting rejection be reconsidered and withdrawn.

### ***Conclusion***

Entry of the above amendment is respectfully solicited. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the allowance of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an additional extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

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Respectfully submitted,

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